DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-865/S-010

Berlex
Attention: Ms. Maria C. Garrigan
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Garrigan:

Please refer to your supplemental new drug application dated October 19, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Betapace (sotalol hydrochloride) 80, 120, 160 and 240 mg Tablets.

We acknowledge receipt of your submissions dated February 16 and June 27, 2001. Your submission of June 27, 2001 constituted a complete response to our January 30, 2001 action letter.

This supplemental new drug application provides for revised labeling to include information from pediatric studies in the Clinical Pharmacology, Precautions, Adverse Reactions and Dosage and Administration sections.
In addition, we note the following changes:

1. In the Black Box, the sentence, "Calculations of creatinine clearance should be calculated prior to dosing." has been changed to, "Creatinine clearance should be calculated prior to dosing."

2. Under the CLINICAL PHARMACOLOGY/Mechanism of Action, the phrase, "slows AV nodal conduction," in the second sentence, has been changed to, "decreases AV nodal conduction."

3. Under the HOW SUPPLIED section, the sentence, "Store at 25^0C with excursions permitted between 15^0-30^0C" has been changed to "Store at 25^0C (77^0F) with excursion permitted between 15^0-30^0C (59^0-86^0F) [See USP Controlled Room Temperature].

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed package insert included in your June 27, 2001 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to

use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Ms. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5333

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Raymond Lipicky

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